

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification ⁶ : A61F 2/06</p>	<p>A1</p>	<p>(11) International Publication Number: WO 95/31945 (43) International Publication Date: 30 November 1995 (30.11.95)</p>
<p>(21) International Application Number: PCT/US95/06228 (22) International Filing Date: 18 May 1995 (18.05.95) (30) Priority Data: 08/246,320 19 May 1994 (19.05.94) US (71) Applicant (for all designated States except US): SCIMED LIFE SYSTEMS, INC. [US/US]; One Scimed Place, Maple Grove, MN 55311 (US). (72) Inventors; and (75) Inventors/Applicants (for US only): BURMEISTER, Paul, H. [US/US]; 8554 Quarles Road North, Maple Grove, MN 55311 (US). EUTENEUER, Charles, L. [US/US]; 1951 Lander Avenue N.E., St. Michael, MN 55376 (US). BROWN, Brian, J. [US/US]; 178 Jandel Avenue N.E., Hanover, MN 55341 (US). FORDENBAUCHER, Paul, J. [US/US]; 3015 James Avenue South, Minneapolis, MN 55408 (US). VRBA, Anthony, C. [US/US]; 1266 88th Place North, Maple Grove, MN 55369 (US). (74) Agents: ARRETT, Oliver, F. et al.; Vidas, Arrett & Steinkraus, Suite 1540, 920 Second Avenue South, Minneapolis, MN 55402 (US).</p>		<p>(81) Designated States: CA, JP, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>
<p>(54) Title: IMPROVED TISSUE SUPPORTING DEVICES</p> <p>(57) Abstract</p> <p>A new multiple component stent (10) which allows for initial self-expansion and subsequent deformation to a final enlarged size. In one embodiment, stent (10) comprises a first resilient element (12) and a second deformable element (14). In another embodiment, stent (30) is made of a first austenite component (32) and a second martensite component (34).</p> <div data-bbox="565 1136 1338 1486"><p>30</p><p>34 (MARTENSITE)</p><p>32 (AUSTENITE)</p></div>		

BEST AVAILABLE COPY

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgyzstan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo	KR	Republic of Korea	SE	Sweden
CH	Switzerland	KZ	Kazakhstan	SI	Slovenia
CI	Côte d'Ivoire	LI	Liechtenstein	SK	Slovakia
CM	Cameroon	LK	Sri Lanka	SN	Senegal
CN	China	LU	Luxembourg	TD	Chad
CS	Czechoslovakia	LV	Latvia	TG	Togo
CZ	Czech Republic	MC	Monaco	TJ	Tajikistan
DE	Germany	MD	Republic of Moldova	TT	Trinidad and Tobago
DK	Denmark	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	US	United States of America
FI	Finland	MN	Mongolia	UZ	Uzbekistan
FR	France			VN	Viet Nam
GA	Gabon				

IMPROVED TISSUE SUPPORTING DEVICES

Background of the Invention

This invention relates to tissue supporting devices in general and most particularly to vascular stents for placement in blood vessels. A primary feature of the devices of this invention is that they are expandable within the body.

In the past, such devices have been provided for implantation within body passageways. These devices have been characterized by the ability to be enlarged radially, often having been introduced into the desired position in the body as by percutaneous techniques or surgical techniques.

These devices are either expanded mechanically, such as by expansion of a balloon positioned inside the device, or are capable of releasing stored energy to self-expand themselves within the body.

The materials which have been used to make up these devices have included ordinary metals, shape memory alloys, various plastics, both biodegradable and not, and the like.

This invention is concerned with the use of these materials in a new multiple component arrangement which allows for initial self-expansion and subsequent deformation to a final enlarged diameter in the body.

Balloon expandable stents do not always expand uniformly around their circumference. As a result, healing may not take place in a consistent manner. If the stent is coated or covered, non-uniform expansion may tear the covering or coating. Additionally, long stents of this type may require long balloons which can be difficult to handle, difficult to size, and may not offer ideal performance in tortuous passages in blood vessels and the like.

Thus, when addressing such issues, self-expandable stents have been thought to be generally more desirable. Unfortunately, one cannot control the degree of expansion and hence the degree of embedment in the vessel wall. It has been determined that a stent must be embedded to some degree to be clinically satisfactory.

The stents of the present invention provide the best features of both of these types of stents without their drawbacks.

-2-

Summary of the Invention

The tissue supporting devices of this invention are generally cylindrical or tubular in overall shape and of such a configuration as to allow radial expansion for enlargement. They are often referred to herein in the general sense as "stents". Furthermore, the devices are comprised of at least one component, element, constituent or portion which exhibits a tendency to self-expand the device to an expanded size and at least one other component, element, constituent or portion which is deformable so as to allow an external force, such as a balloon positioned within the body of the device, to further expand it to a final, larger desired expanded size. The terms "component", "element", "constituent" and "portion" are often referred to herein collectively as "portion".

Preferably, the devices of the invention are made of metal and most preferably of shape memory alloys.

In one embodiment, a first portion is a resilient spring-like metal for self-expansion and a second portion is a deformable metal for final sizing. In a more preferred shape memory embodiment, a first portion is a self-expanding austenitic one and a second is a martensitic one capable of deformation. In the case of shape memory embodiments the "portions" may be discrete or merely different phases of an alloy.

The most preferred embodiment of the invention is a stent, preferably of shape memory alloy. The most preferred shape memory alloy is Ni-Ti, although any of the other known shape memory alloys may be used as well. Such other alloys include: Au-Cd, Cu-Zn, In-Ti, Cu-Zn-Al, Ti-Nb, Au-Cu-Zn, Cu-Zn-Sn, Cu-Zn-Si, Cu-Al-Ni, Ag-Cd, Cu-Sn, Cu-Zn-Ga, Ni-Al, Fe-Pt, U-Nb, Ti-Pd-Ni, Fe-Mn-Si, and the like. These alloys may also be doped with small amounts of other elements for various property modifications as may be desired and as is known in the art.

The invention will be specifically described hereinbelow with reference to stents, a preferred embodiment of the invention although it is broadly applicable to tissue support devices in general.

Brief Description of the Figures

Figure 1 is a braided stent according to one embodiment of this invention.

Figure 2 is a graph showing the martensitic/austenitic temperature transformation curve and the superelastic area of a shape memory alloy.

Figure 3 is an end view of a layered stent having two discrete components according to one aspect of this invention.

Figures 4a and 4b are graphs showing the martensitic/austenitic temperature transformation curves of the layers in the stent of Figure 3.

Figure 5a and 5b are views of another embodiment of the invention comprised of alternating rings of shape memory alloy.

Figure 6 is a showing of a stent fragment of a braided version of a shape memory stent of this invention.

Figure 7 is a graph showing a temperature window for a shape memory alloy to be used in yet another stent version of this invention.

Figure 7a is a graph showing expansion of a stent with temperature.

Figure 7b is a graph of the same type, the stent having been cold-worked.

Figure 7c is a graph of the same type, the stent having had pseudoelastic pretraining.

Figure 7d is a graph of the same type, the stent having amnesia inducement.

Figures 8-11 show various expandable configurations (closed and open) illustrated in fragment which may be used in the stents of this invention.

Figures 9a and 9b show a preferred embodiment of an articulated stent.

Figure 12 shows another version of an expandable stent of the invention.

Figure 13 shows yet another version of a stent which may be used with the invention.

Figure 14 is a schematic showing of a braided stent made up of a plurality of strands.

Figure 15 is a detail of a single strand from the stent of Figure 14 showing that the strand is made up of a plurality of wires of two different types.

-4-

Figure 16 is a cross-sectional view taken along line 16-16 of Figure 15 showing the two different types of wire.

Detailed Description of the Invention

5 Preferred embodiments of this invention are described below with particular reference to the accompanying drawing Figures.

Referring first to the embodiment shown in Figure 1, a stent 10 is shown comprised of braided or interwoven metal strands 12 and 14. Strands 12 are of a resilient spring-like metal such as spring steel, Elgiloy for example. Preferably,
10 strands 12 are spirally extending in the same direction, spiraling to the right as seen in Figure 1. Strands 14 are of a deformable or annealed metal such as stainless steel and are preferably spiraled in the opposite direction as strands 12, as shown in Figure 1.

Given such a stent construction of two components *i.e.*, strands 12
15 and 14, it can be seen that stent 10 may be readily loaded on a catheter as by placing it over an uninflated balloon on a balloon catheter and compressing it tightly around the balloon and then placing a sheath over the stent to hold it in place during the transluminal placement procedure. Once in place, the sheath is removed, for example slid back, to expose the stent, allowing it to self-expand by force of the
20 resilient strands 12 to substantially assume a self-expanded shape/size. Some self-expansion may be restrained if held back by strands 14. To finally adjust the size of the stent, the balloon may be expanded by inflation from within the stent to exert an outward radial force on the stent and further enlarge it by stretching and deforming the deformable metal of strands 14. This may be aided by building into strands 14,
25 a series of readily deformable structures or means such as bends or kinks 16 as shown in Figure 1. It can be seen that a permanent adjustable size beyond the self-expanded size may be obtained with this embodiment. It is to be noted that many configurations other than braided may be readily devised to take advantage of this two component concept, including various of the subsequent configurations described
30 hereinbelow. Also, it should be noted that, although not preferred, the stent may be initially deployed without a balloon; the balloon following on a separate catheter.

Referring now to subsequent features, other preferred embodiments of the invention will be described which make use of shape memory alloys and some of

-5-

their unique properties, primarily their special types of deformation i.e., shape memory deformation in martensite and/or superelastic deformation in austenite.

The term "superelasticity" is used to describe the property of certain shape memory alloys to return to their original shape upon unloading after a substantially deformation while in their austenitic state. Superelastic alloys can be strained while in their austenitic state more than ordinary spring materials without being plastically deformed. This unusually large elasticity in the austenitic state is also called "pseudoelasticity", because the mechanism is nonconventional in nature, or is also sometimes referred to as "transformational superelasticity" because it is caused by a stress induced phase transformation. Alloys that show superelasticity also undergo a thermoelastic martensitic transformation which is also the prerequisite for the shape memory effect. Superelasticity and shape memory effects are therefore closely related. Superelasticity can even be considered part of the shape memory effect.

The shape memory and superelasticity effects are particularly pronounced in Ni-Ti alloys. This application will therefore focus on these alloys as the preferred shape memory alloys. The shape memory effect in Ni-Ti alloys has been described many times and is well known.

In near-equiatomic Ni-Ti alloys, martensite forms on cooling from the body centered cubic high temperature phase, termed austenite, by a shear type of process. This martensitic phase is heavily twinned. In the absence of any externally applied force transformation takes place with almost no external macroscopic shape change. The martensite can be easily deformed by a "flipping over" type of shear until a single orientation is achieved. This process is also called "detwinning".

If a deformed martensite is now heated, it reverts to austenite. The crystallographic restrictions are such that it transforms back to the initial orientation thereby restoring the original shape. Thus, if a straight piece of wire in the austenitic condition is cooled to form martensite it remains straight. If it is now deformed by bending, the twinned martensite is converted to deformed martensite. On heating, the transformation back to austenite occurs and the bent wire becomes straight again. This process illustrates the shape memory deformation referred to above.

-6-

The transformation from austenite to martensite and the reverse transformation from martensite to austenite do not take place at the same temperature. A plot of the volume fraction of austenite as a function of temperature provides a curve of the type shown schematically in Fig. 2. The complete transformation cycle is characterized by the following temperatures: austenite start temperature (A_s), austenite finish temperature (A_f), both of which are involved in the first part (1) of an increasing temperature cycle and martensite start temperature (M_s) and martensite finish temperature (M_f), both of which are involved in the second part (2) of a decreasing temperature cycle.

Figure 2 represents the transformation cycle without applied stress. However, if a stress is applied in the temperature range between A_s and M_d , martensite can be stress-induced. Stress induced martensite is deformed by detwinning as described above. Less energy is needed to stress induce and deform martensite than to deform the austenite by conventional mechanisms. Up to about 8% strain can be accommodated by this process (single crystals of specific alloys can show as much as about 25% pseudoelastic strain in certain directions). As austenite is the thermodynamically stable phase at temperatures between A_s and M_d under no-load conditions, the material springs back into its original shape when the stress is no longer applied.

It becomes increasingly difficult to stress-induce martensite at increasing temperatures above A_f . Eventually, it is easier to deform the material by conventional mechanisms (movement of the dislocation, slip) than by inducing and deforming martensite. The temperature at which martensite can no longer be stress-induced is called M_d . Above M_d , Ni-Ti alloys are deformed like ordinary materials by slipping.

Additional information regarding shape memory alloys is found in the following references, all of which are incorporated fully herein by reference:

"Super Elastic Nickel-Titanium Wires" by Dieter Stöckel and Weikang Yu of Raychem Corporation, Menlo Park, California, copy received November 1992;

Metals Handbook, Tenth Edition, Vol. 2, *Properties and Selection: Nonferrous Alloys and Special-Purpose Materials*, "Shape Memory Alloys" by Hodgson, Wu and Biermann, pp. 897 - 902; and,

-7-

In Press, *Titanium Handbook*, ASM (1994), Section entitled
"Structure and Properties of Ti-Ni Alloys" by T.W. Duerig and A.R.
Pelton.

5 Since the most preferred shape memory alloy is Ni-Ti, the martensitic
state of this alloy may be used to advantage in the two component concept of this
invention.

For example, with reference to Figure 3, a layered construction may
be provided in a stent 30 (shown in end view) which is generally a hollow
cylindrical or tubular body in shape but which may be formed in a wide variety of
10 specific configurations or patterns to foster radial expansion of the body as
exemplified in Figures 1, 5, 6 and in subsequent Figures 8-11.

Stent 30 is comprised of at least two layers 32 and 34, one of which
32 is a Ni-Ti alloy (50.8 atomic wt. % Ni, balance Ti, transition temperature of
 $A_r=0^\circ\text{C}$) and normally in the austenitic state, the other of which 34 is a Ni-Ti
15 (49.4 atomic wt. % Ni, balance Ti, transition temperature $A_r = 60^\circ\text{C}$) and
normally in the martensitic state. Preferably, the inner layer is 32 and the outer
layer is 34. However, this may be reversed and also a plurality of layers,
alternating or otherwise, may be utilized in this particular embodiment.

Stent 30 is made to a fabricated size and shape (parent shape) which
20 provides austenitic layer 32 its parent shape and size *i.e.*, its superelastic high
temperature shape and size. Obviously, in its as fabricated condition, the Ni-Ti
alloy of austenitic layer 32 is selected so as to have a transition temperature range
between its austenitic and martensitic states which is lower than body temperature as
to ensure that in the body and at body temperatures the austenitic state will always
25 prevail.

On the other hand, martensitic layer 34 is of a Ni-Ti alloy having a
transition temperature range significantly greater than body temperature so as to
ensure that under body conditions the martensitic state will always prevail and the
alloy will never transform to austenite in stent use. This is shown in the graphs of
30 Figure 4a and 4b which demonstrate the relative transition temperatures of layers 32
and 34, respectively for purposes of this invention. It can be seen from these graphs
that the normal condition of layer 32 (Figure 4a) at body temperatures and higher is

-8-

the austenitic state while the normal condition of layer 34 (Figure 4b) at body temperatures is martensitic.

To manufacture the layered construction, one may make the austenitic portion with any standard metallurgical technique and vapor deposit the martensitic portion on its surface. Other manufacturing techniques such as diffusion bonding, welding, ion beam deposition, and various others will be apparent to those familiar with this art.

Such a stent may be compressed or constrained (deformed to a small diameter) onto a balloon catheter as described for the previous embodiment and captured within a sheath. During the constraintment, austenitic layer 32 may stress induce to a martensitic state. In the alternative, the stent may be cooled below the transition temperature of layer 32 to facilitate its deformation and constraintment. Martensitic layer 34 merely undergoes deformation. Thus the stent may be "loaded" onto a balloon catheter. However, with temperature changes occurring up to body temperature, layer 32 will remain martensite until the constraint is removed. When released in place in the body, stent 30 will expand to a percentage of its self-expanded size and shape due to the transformation of layer 32 from martensite to austenite at which point the balloon may be used to radially expand the stent to a greater permanent diameter by deforming martensitic layer 34. On the other hand, initial deployment can take place without a balloon which may be separately inserted after deployment.

The two component concept of the invention in the layered embodiment of Figure 3 requires both the martensitic and austenitic phase characteristics of shape memory alloy(s) in the two discrete components 32 and 34.

Preferably, the stent is fabricated in such a way that the austenitic layer 32 tends to self-expand stent 30 to a predetermined fabricated diameter (parent shape). The martensitic layer 34 tends to hold back this self-expansion, preventing full expansion. For example, the stent may only be able to self-expand to 75% of its full possible diameter (as determined by the austenitic layer). Therefore, expansion beyond 75% is accomplished by an applied external force, as by the balloon inside the stent. It is suggested that the stent not be expanded beyond its normal fabricated diameter for the austenitic layer 32 will have the tendency of making the stent diameter smaller as it tries to recover its fabricated diameter

-9-

(parent shape). If the stent is subjected to a temperature above body temperature and above the transition temperature of the martensitic layer (which is clinically unlikely), the stent will self-expand to the fabricated diameter only. Depending on design size there are thus provided permanent stents capable of fulfilling any needed
5 range of sizes with an adjustable sizing capability.

As is known in the art, the desired properties of the shape memory alloys required for use in this invention may be obtained by alloy composition and working and heat treatment of the alloys, in various combinations or singly.

Manufacturing techniques influence the phase characteristics of the
10 material. Alloy composition, work history, and heat treatment all influence the final characteristics. At a specific operating temperature, say body temperature, the austenite phase material will have a transition temperature below body temperature (i.e., $A_f=0^\circ\text{C}$). The material is capable of taking high strains and recovering after the load is released. The martensite phase material will have a higher transition
15 temperature than body temperature (i.e., $A_f=60^\circ\text{C}$), and is characteristically soft and pliable and retains the deformed shape after load removal. This martensite deformation is caused by detwinning, not the typical plastic deformation, or yielding, of crystal slip.

With reference to Figures 5 and 6, other stent constructions are shown
20 which are similar to the layered version of Figure 3 in so far as utilization of the two component concept of this invention is concerned.

Figure 5a and 5b shows a stent 50 made up of alternating expandable rings 52 and 54 of austenitic and martensitic alloys, respectively, analogous to layers 32 and 34 of the Figure 3 embodiment. Rings 52 and 54 for example are
25 interconnected by strut members 56 which may be of any material capable of rigidly holding the rings together. Other interconnector means may be used. As can be seen in Figure 5b, the placement of strut members 56 does not require them to take part in the radial expansion of the stent and they can therefore be of a relatively ordinary material such as stainless steel.

30 Referring now to Figure 6, a braided or interwoven construction is shown similar in construction to that of the embodiment of Figure 1. In this embodiment, strands 62 extending to the right in Figure 6 are an alloy in the

-10-

austenitic state whereas strands 64 extending to the left in Figure 6 are an alloy in the martensitic state.

Referring now to the graph of Figure 7, it is demonstrated that the two component concept of the invention may be embodied in two phases, i.e., components of a single shape memory alloy and need not be in the form of two discrete components such as layers, members, wires, etc. In the graph of Figure 7, it can be seen that an alloy composition can be selected such that it has a phase transition temperature window that bounds the proposed operating temperatures of the stent, such as the normal body temperature range. Within this transitional window or zone, the material undergoes the phase transition and is effectively compositionally comprised of a ratio of austenitic to martensitic phase depending on the temperature of the stent. This ratio should be selected so as to provide sufficient radial force from the austenite phase while still allowing for further expansion of the martensite phase with a mechanical expansion means such as a balloon. Selecting body temperature as the operating temperature, a Ni-Ti alloy of about 50/50 atomic wt. % composition (range about 49/51%) will provide an acceptable "window" for this embodiment, the two components are the austenite and martensite phases of the nitinol.

The method of making a stent may be described as follows. Age the shape memory material (Ni Ti) until body temperature falls somewhere within the transformation window. Therefore the stent will not fully recover to its high temperature shape at body temperature. An example of this technique is described below.

A stent of tubular 50.8% Ni balance Ti was prepared having a 1.5 mm diameter. It was substantially all austenite at room temperature, the A_r being about 15-20°C and therefore being superelastic at room temperature. The stent was cooled to below room temperature to form substantially all martensite and mechanically expanded to 4.7 mm in diameter. It was maintained at the 4.7 mm in diameter and heat treated at 500°C for 30 minutes and water quenched. Finally, it was again cooled to below room temperature to form substantially all martensite and compressed to a diameter of 1.5 mm. After deployment and at body temperature the stent has a diameter of 3.5 mm. At about 70% of full expansion, i.e., about 40°C it had a diameter of 4.5 mm and at 42°C it had a fully expanded diameter of 4.7 mm.

-11-

This method works fairly well, but due to the slope of the temperature versus diameter plot being extremely vertical at body temperature, a small change in body temperature, or manufacturing control, can have a large impact on the actual self expansion diameter. As can be seen from Figure 7, the slope of the line
5 between A_f and A_s is rather steep with small changes in temperature leading to large changes in percent austenite and consequently large changes in diameter of a stent made of such an alloy. Figure 7a shows a temperature versus diameter plot. Three methods of modifying the slope of the line on the temperature versus diameter graph are cold work, pseudoelastic prestraining, and amnesia inducement, illustrated in
10 Figures 7b, 7c and 7d, respectively.

COLD WORK

Residual cold work in nitinol draws out or masks the point of A_f on the diameter versus the temperature curve. This is seen by the sluggish increase in diameter as temperature increases in the last 20-30% of recover. By utilizing the
15 effects of cold work, the effects of temperature change on diameter can be reduced in the last 20 to 30% of stent expansion. Shown in Figure 7b is an example of a temperature versus diameter plot for a cold worked part. Figure 7a above shows an example of a part without cold work.

PSEUDOELASTIC PRETRAINING

Utilizing the effects of pseudoelastic prestraining (S. Eucken and T.W. Duerig, *ACTA Metal*, Vol. 37, No. 8, pp 2245-2252, 1989) one can create two distinct plateaus in the stress-strain behavior. This difference in stress strain behaviors can be directly linked to two distinct A_f temperatures for the two plateaus. By placing the transition between the two plateaus at the transition from self
20 expanding to balloon expanding, i.e., 70%, one can control the characteristics of the stent at body temperature. The goal would be to place the A_f temperature for the first plateau (from maximum compression to 70% expansion) below body temperature such that the stent has self expanding characteristics. The A_f
25 temperature for the second plateau would be above body temperature such that there is no additional self expansion in this region (70 to 100% expansion) a mechanical device, like a balloon, can then be used to custom size the stent between 70% and
30 100% of the high temperature shape. Results of such a technique is shown in Figure 7c.

-12-

AMNESIA INDUCEMENT

One of the characteristics of nitinol is cycle amnesia. This was also discussed about in the article referred to immediately above. As nitinol is cycled from its heat set shape as shown in Figure 7d, there is an increase in the amount of amnesia to recover to the heat set shape with each cycle. As long as this amnesia is not caused by permanent plastic deformation, the amnesia can be removed by heating the part above M_d . This shows there is martensite left in the part after cycling which is preventing full recovery in the austenite phase (just above A_f). This presence of non recoverable martensite (below M_d) is what may be used for the balloon expansion region of the stent.

Figures 8-11 represent examples of various expandable configurations (a = closed, b = expanded) which may be incorporated into the devices of this invention. The version shown in Figures 10a and 10b may be modified as shown in Figures 10c and 10d (closed and open, respectively) by omitting portions (indicated at 100 in Figures 10c and 10d) as to render the stent flexible for articulation. This may be done to other of the structures as well to improve flexibility.

Yet another version of a device incorporating the two component concept of the invention is shown in Figure 12. In this embodiment, a fragment of a stent 110 is shown. The stent includes a self-expanding component 112 and a deformable, external force expandable component 114. Self expanding component 112 may be resilient spring-like metal such a stainless steel or it may preferably be a shape memory alloy in the austenitic state. Component 114 may be any deformable metal or the like such as annealed stainless steel or preferably a shape memory alloy in the martensitic state. The two components may simply be mechanically, welded or bonded together. Functions and operations are as described hereinabove.

Referring to Figure 13 a version analogous to the embodiment of Figure 12 is shown in which the two component concept is again embodied as different zones or portions of a single metal material.

As shown in Figure 13, a stent 120 (fragment showing) is of a self-expanding component 122 and a deformable component 124, both of which may be a single metal as spring steel or austenitic Ni-Ti which has been appropriately treated with respect to component 124 as by localized heat treatment or the like to alter the characteristics of the material of the 122 component so as to render it deformable or

-13-

martensitic, depending on whether it is merely resilient or is austenitic. Again, function and operation are the same as with other embodiments.

Referring now to Figures 14-16, a multi-strand braided stent is shown in Figure 15. Each strand 150 in the stent is a micro-cable. That is, each strand is made up of a plurality of wires 152 and 154 as is seen in Figures 15 and 16. Each of the wires 152 and 154 consists of two different nitinol alloys as seen best in Figure 16, or one nitinol and one ordinary metal such as stainless steel, platinum or tantalum. The latter two would provide enhanced radiopacity. One nitinol alloy wire 154 has an austenitic finish (A_s) temperature less than body temperature. The other wire 152 could be nitinol having an A_s (austenitic start) greater than body temperature. Also, it could be an ordinary metal. Additionally, one or more of the strands may be of a biodegradable material such as a plastic or may be of a material including an absorbable drug.

Since the two alloys are stranded into micro-cable one does not have to engage in selective, discrete heat treating methods to produce both shape memory and martensitic effects.

Radiopaque portions or coatings may be included on any parts of these stents as is known in the prior art.

While this invention may be embodied in many different forms, there are described in detail herein specific preferred embodiments of the invention. This description is an exemplification of the principles of the invention and is not intended to limit the invention to the particular embodiments illustrated.

The above Examples and disclosure are intended to be illustrative and not exhaustive. These examples and description will suggest many variations and alternatives to one of ordinary skill in this art. All these alternatives and variations are intended to be included within the scope of the attached claims. Those familiar with the art may recognize other equivalents to the specific embodiments described herein which equivalents are also intended to be encompassed by the claims attached hereto.

WHAT IS CLAIMED

1. As a tissue supporting device a constrainable, self-expanding member of generally tubular shape comprised of first and second portions; first portion being
5 of a resilient material; the second portion being of a deformable and substantially less resilient material than the first portion; the member being constrainable to a deployable diameter in preparation for insertion into a patient; the device being self-expanding when unconstrained to an initially deployed diameter due to the resiliency of the first portion; the portions being so associated with respect to each other and
10 the member such that the device may be further deformed due to the deformability of the second portion by an external force to radially enlarge the member to an enlarged fully deployed diameter for providing permanent tissue support.
2. The device of claim 1 wherein the first and second portions are of metal.
- 15 3. The device of claim 2 wherein the first portion is a spring metal and the second portion is an annealed metal.
4. The device of claim 1 wherein the first and second portions are in the form of layers.
5. The device of claim 1 wherein the first and second portions are
20 discrete portions in the circumference of the device body.
6. The device of claim 1 wherein the first and second portions are of shape memory alloy, austenite and martensite, respectively.
7. The device of claim 1 wherein the first and second portions are strands.
- 25 8. The device of claim 1 wherein the first and second portions are of a shape memory alloy.
9. A permanent self-expanding stent having a generally tubular body of a predetermined fabricated diameter comprised, at about normal body temperatures, of a shape-memory, superelastic, austenitic alloy portion and a shape memory,
30 martensitic alloy portion, the superelastic austenitic alloy portion having a transition temperature from martensitic to austenitic less than body temperature while the martensitic alloy portion has a transition temperature from martensitic to austenitic substantially greater than body temperature, the martensitic alloy portion and

-15-

superelastic austenitic alloy portion being constructed, arranged and associated with respect to each other in comprising the stent such that the two alloy portions act in combination to allow, upon transformation of the austenitic alloy portion to martensitic at a temperature below the transition temperature, constraint of the stent
5 to a deployment diameter smaller than the predetermined fabricated diameter and upon transformation of the austenite alloy portion from martensite back to austenite to self-expand the stent back to about the predetermined fabricated diameter at temperatures in excess of the transition temperature of the austenitic superelastic portion, the shape memory of the superelastic austenitic portion tending to form the
10 stent to a larger diameter due to its shape memory but being restrained therefrom by the martensitic alloy portion whereby the austenitic alloy portion can be deformed by external force without plastic deformation along with the martensitic portion to an enlarged stent diameter beyond that of the self-expanded diameter.

10. The stent of claim 9 wherein the first and second portions are in the
15 form of layers in overlying relationship.

11. The stent of claim 9 wherein the first and second portions are different phases in an alloy.

12. The stent of claim 9 wherein the first and second portions are in the form of strands.

20 13. The stent of claim 9 wherein the first and second portions are in the form of longitudinally arranged interconnected alternating rings.

14. The stent of claim 9 comprised of a plurality of cable-like strands and wherein each strand is comprised of a plurality of wires some of which are of the first portion and some of which are of the second portion.

25 15. A permanent self-expanding stent having a generally tubular body of a predetermined fabricated diameter-parent shape, comprised, at about normal body temperatures, of a shape-memory, superelastic, austenite phase portion and a shape memory, martensite phase portion, the superelastic austenite phase portion having a transition temperature from martensitic to austenitic less than body temperature
30 while the martensite phase portion has a transition temperature from martensitic to austenitic substantially greater than body temperature, the martensite phase portion and superelastic austenite phase portion being constructed, arranged and associated with respect to each other in comprising the stent such that the two portions act in

-16-

combination to allow, upon transformation of the austenite phase portion to martensite, constraint of the stent to a deployment diameter smaller than the predetermined fabricated diameter and upon transformation of the austenite phase portion from martensite back to austenite to self-expand the stent back toward the
5 predetermined fabricated diameter at temperatures in excess of the transition temperature of the austenite superelastic portion, the shape memory of the superelastic austenitic portion tending to form the stent to the fabricated diameter parent shape due to its shape memory but being restrained therefrom by the martensite portion whereby the austenite portion recovery back toward the fabricated
10 diameter can be assisted by external force along with the deforming of the martensitic portion without slip deformation to an enlarged stent diameter beyond that of the restrained self-expanded diameter.

16. As a tissue supporting device, a constrainable, self-expanding member of generally tubular shape comprised of first and second portions of nickel-titanium
15 shape-memory alloy; the first portion alloy having martensitic and austenitic superelastic shape memory metallurgical states and a transition temperature therebetween, the transition temperature being at less than body temperature; the second portion alloy having martensitic and austenitic metallurgical states and a transition temperature therebetween, the transition temperature being substantially
20 higher than body temperature, said first portion alloy being transformable from austenitic to the martensitic state when cooled below its transition temperature so as to render both alloy portions in the martensitic state whereby the member is constrainable to a deployable diameter in preparation for insertion into a patient, during which the first portion alloy may transform to the austenitic state while
25 constrained, the second portion alloy being and remaining in the martensitic state; the stent being self-expanding at body temperature when unconstrained to an initially deployed diameter due to the first portion alloy being in the austenitic state and the second portion alloy being in the martensitic state, the alloy portions being so associated with respect to each other and the member such that the second portion
30 alloy restrains the first portion so that the member assumed the initially deployed diameter, because of the restriction of the austenitic superelastic alloy from the full exercise of its shape memory and whereby the alloy portions may be further

-17-

deformed by an external force to radially enlarge the member to an enlarged fully deployed diameter for providing permanent tissue support.

17. A self-expanding stent comprised of at least two components arranged for coaction, the first component being substantially austenite and the second being
5 substantially martensite.

18. The stent of claim 16 wherein the first component is a nitinol alloy.

19. The stent of claim 16 wherein the first component is superelastic and the second component is any deformable material.

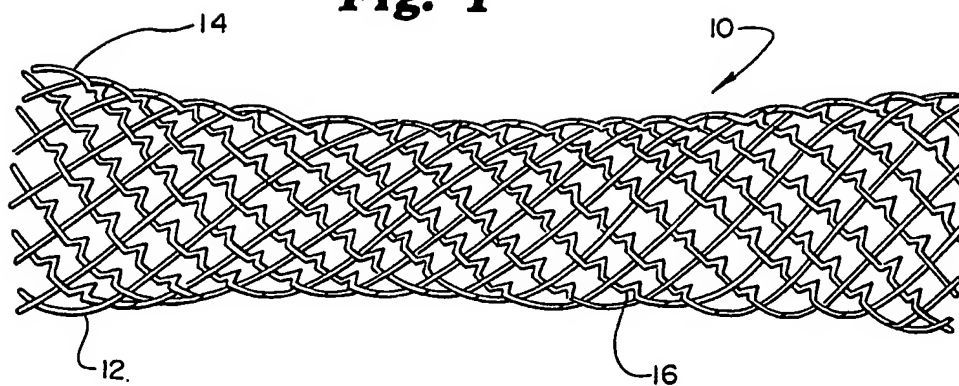
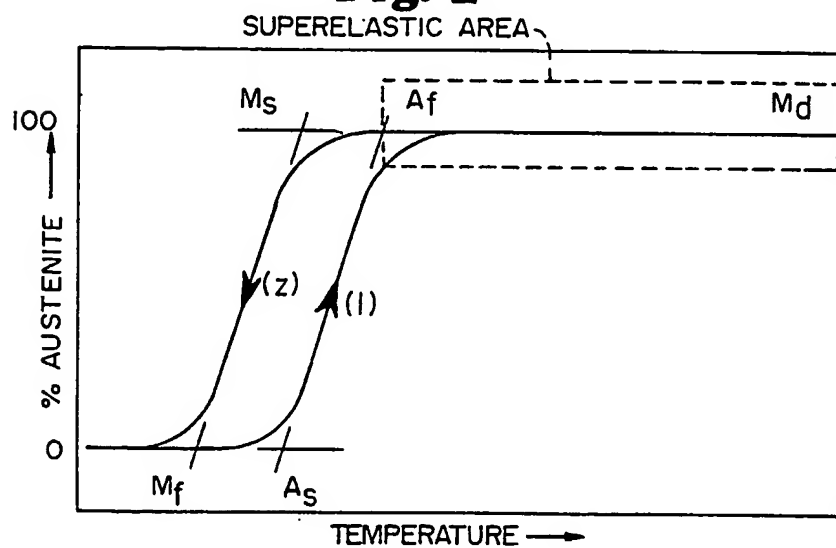
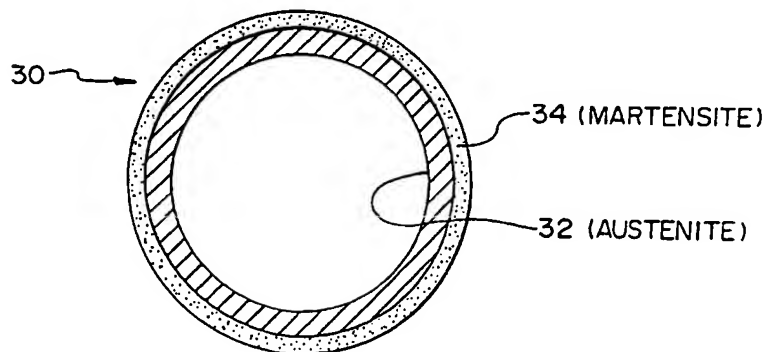
20. As a tissue supporting device, a constrainable, self-expanding member
10 of generally tubular shape comprised of nickel-titanium shape memory alloy containing components of both martensite and austenite phases, the transition temperature being at about body temperature, said alloy being transformable to the fully martensitic state when cooled below its transition temperature so as to render it to the martensitic state whereby the member is more easily constrainable to a
15 deployable diameter in preparation for insertion into a patient; the stent being self-expanding at body temperature when unconstrained to an initially deployed diameter due to a portion of the alloy being in the austenitic state and a portion of the alloy being in the martensitic state, the alloy portions being so associated with respect to each other and the member such that the member assumes the initially deployed
20 diameter, upon self-expansion and the alloy portions may be further deformed by an external force to radially enlarge the member to an enlarged fully deployed diameter for providing permanent tissue support.

21. A permanent self expanding stent having a generally tubular body of a predetermined fabricated diameter-parent shape, comprised, at about normal body
25 temperatures, of a shape-memory, superelastic, austenite phase portion and a shape memory martensite phase portion, the superelastic austenite phase portion having a transition temperature from martensitic to austenitic less than body temperature while martensite phase portion has a transition temperature from martensitic to austenitic substantially greater than body temperature, the martensite phase portion
30 and superelastic austenite phase portion being constructed, arranged and associated with respect to each other in comprising the stent such that the two portions act independently to allow, upon transformation of the austenite phase portion to martensite, constraint of both of the original phase portions of the stent to a

-18-

- deployment diameter smaller than the predetermined fabricated diameter and upon transformation of the austenite phase portion from martensite back to austenite to self-expand the stent back to the austenite phase portion predetermined fabricated diameter at temperatures in excess of the transition temperature of the austenite
- 5 superelastic portion, the shape memory of the superelastic austenitic portion tending to form the austenitic portions of the stent to the fabricated diameter parent shape due to its shape memory, with the martensitic portions remaining in the deployment shape, additional recovery back toward the stent fabricated diameter parent shape can be assisted by an external force deforming the martensitic portion without slip
- 10 deformation to an enlarged stent diameter beyond that of the self-expanded austenitic portion diameter, but not greater than the stent fabricated diameter parent shape.

1/13

Fig. 1**Fig. 2****Fig. 3**

2/13

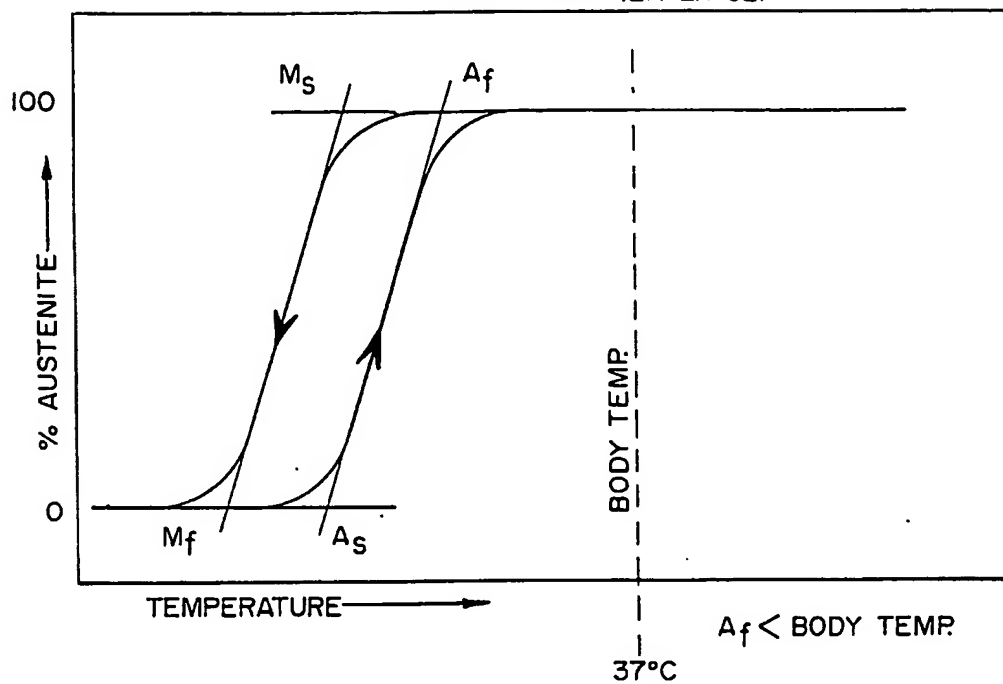
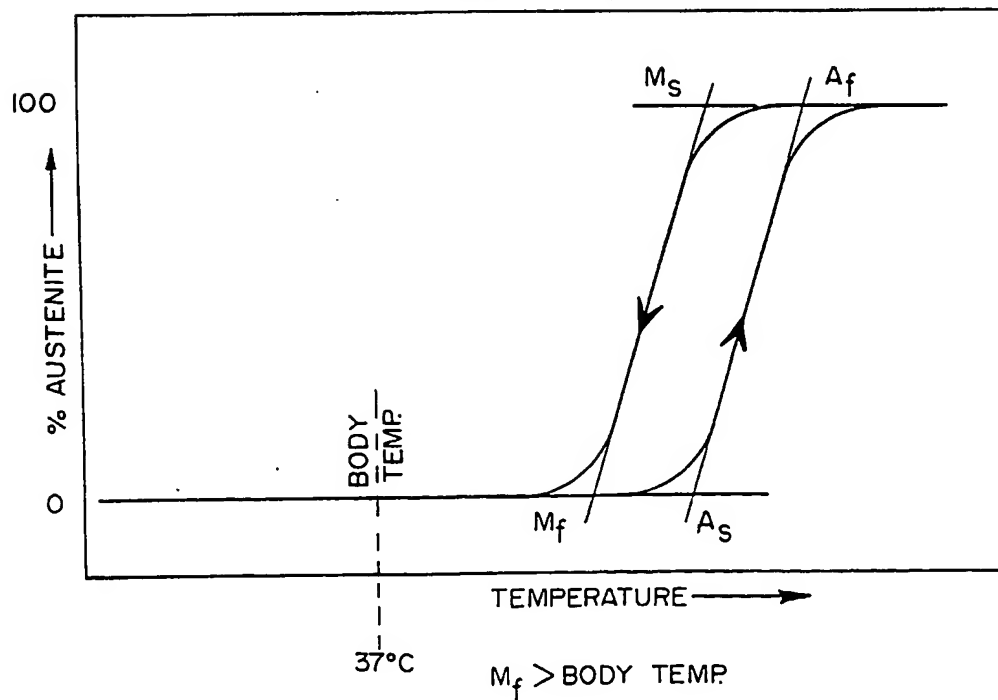
Fig. 4a (LAYER 32)**Fig. 4b** (LAYER 34)

Fig. 5a

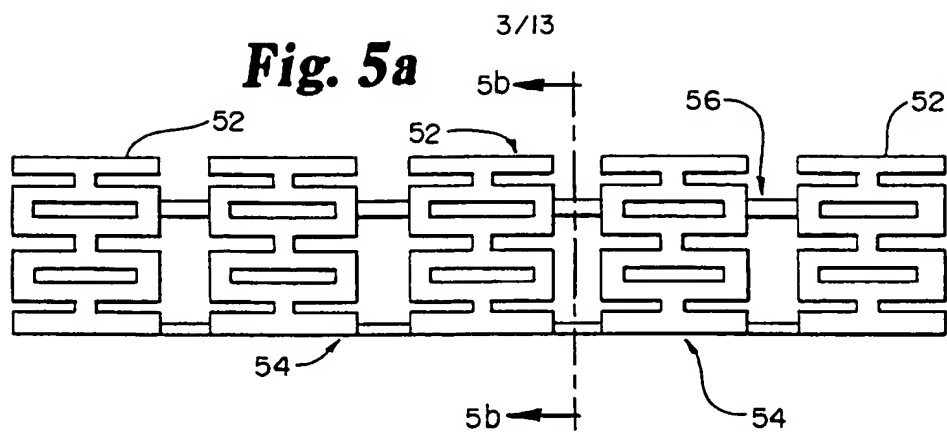


Fig. 5b

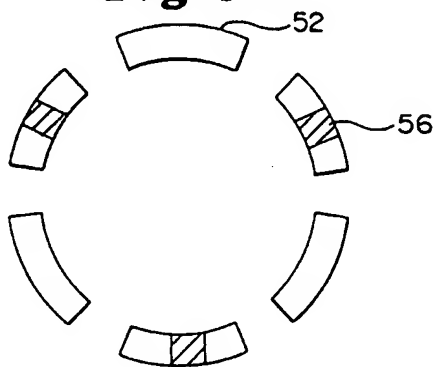
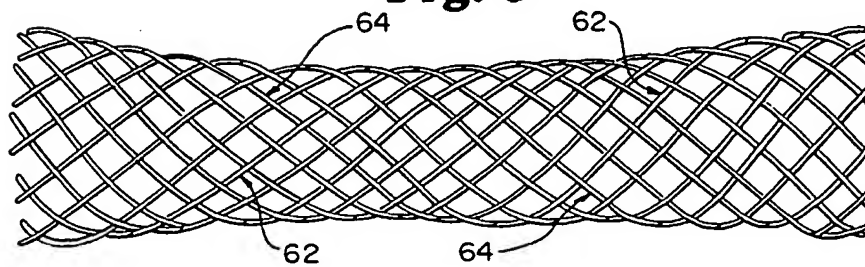
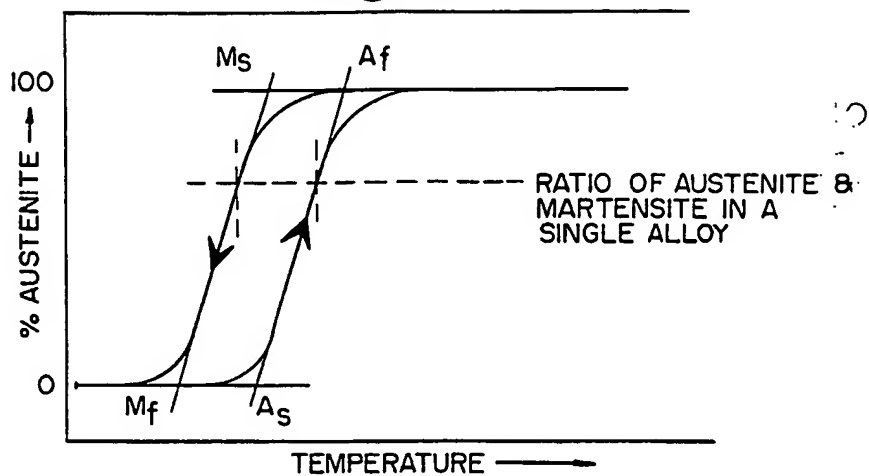
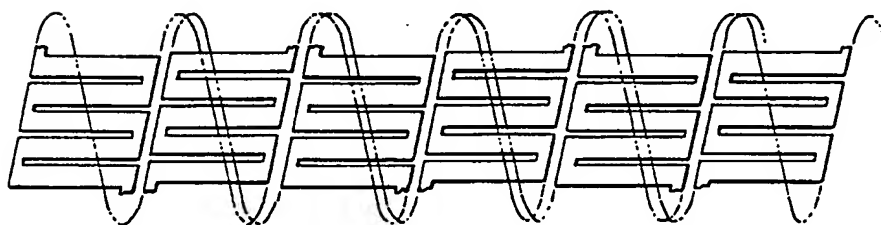
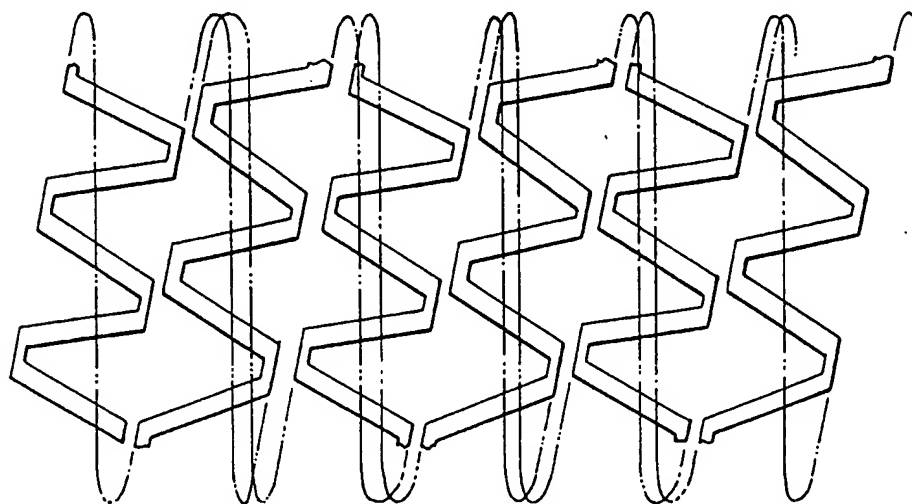


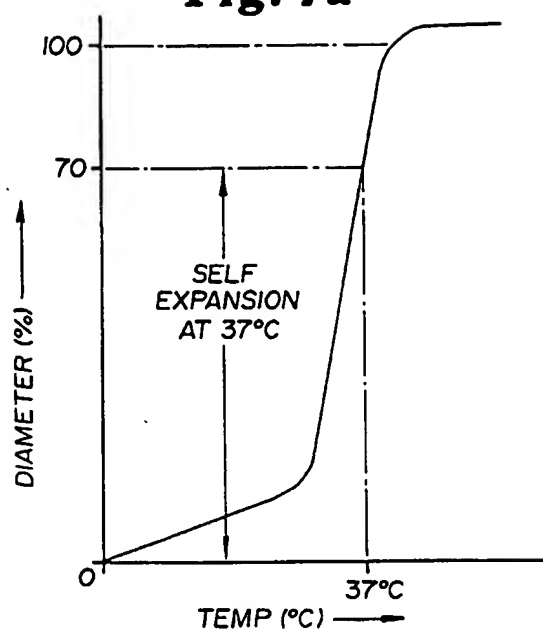
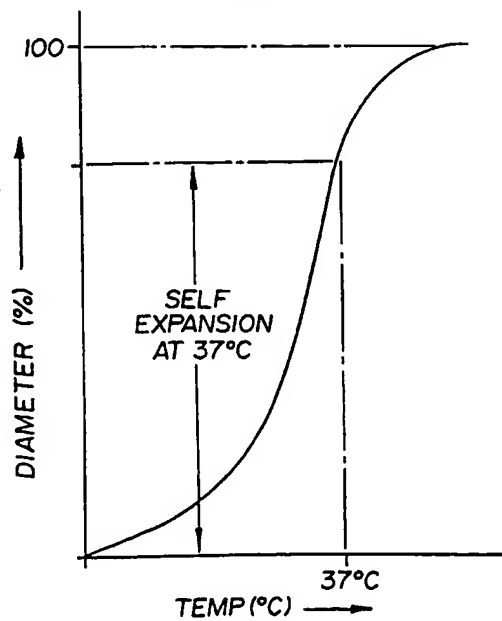
Fig. 6



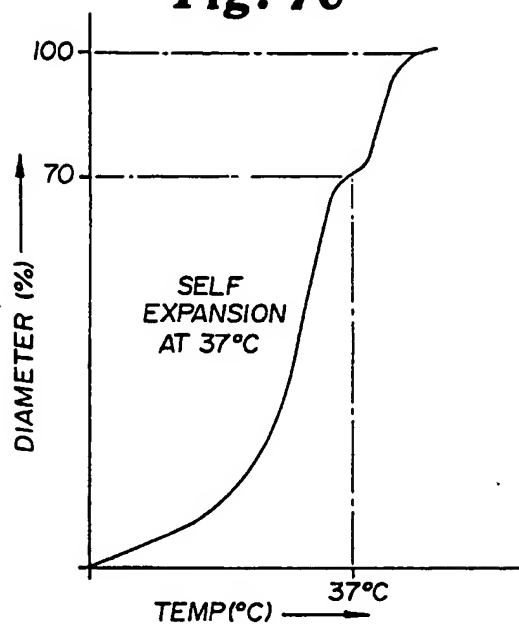
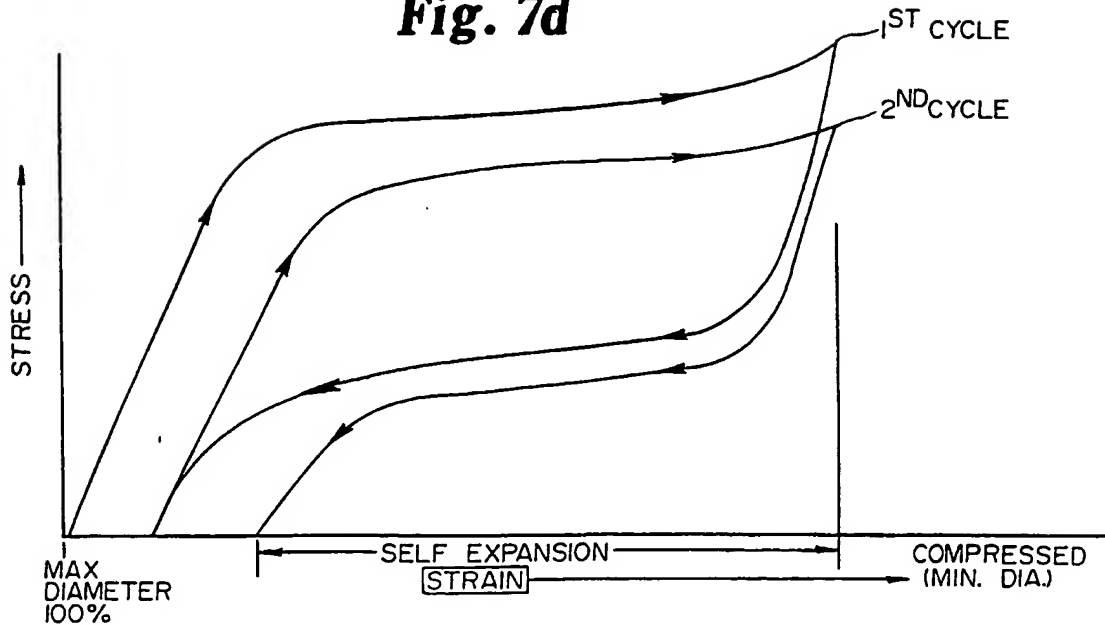
4/13

Fig. 7**Fig. 8a****Fig. 8b**

5/13

Fig. 7a**Fig. 7b**

6/13

Fig. 7c**Fig. 7d**

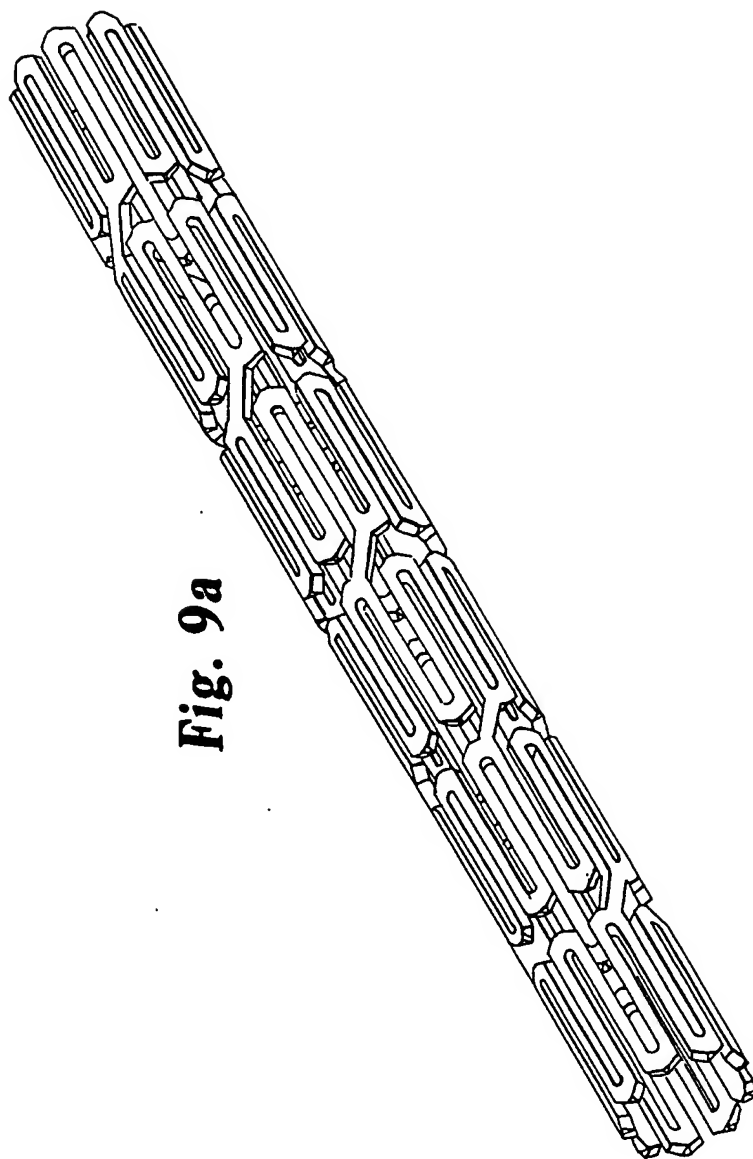


Fig. 9a

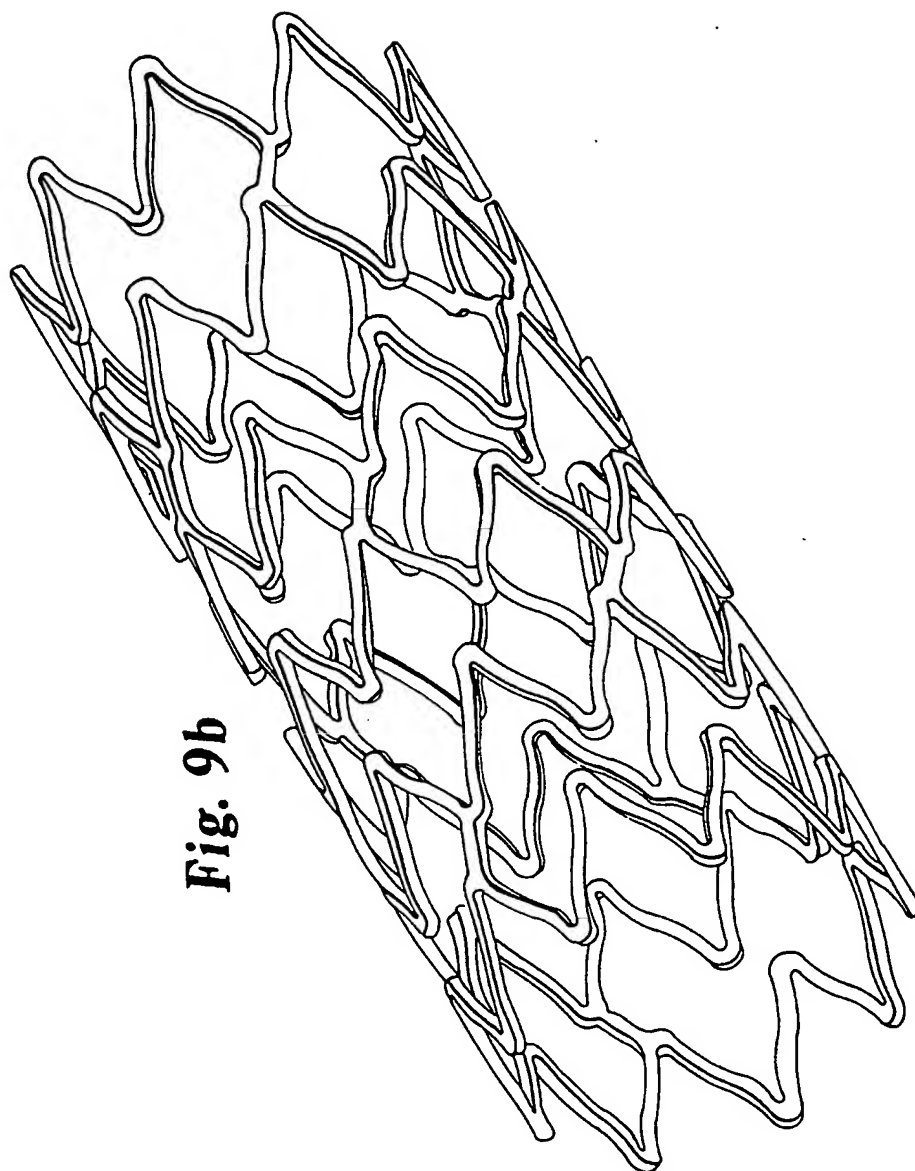


Fig. 9b

9/13

Fig. 10a

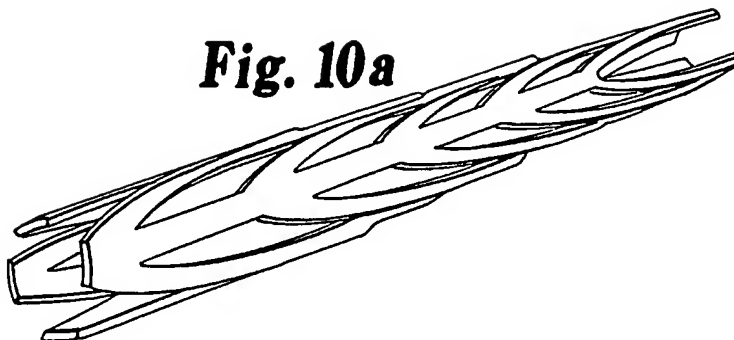
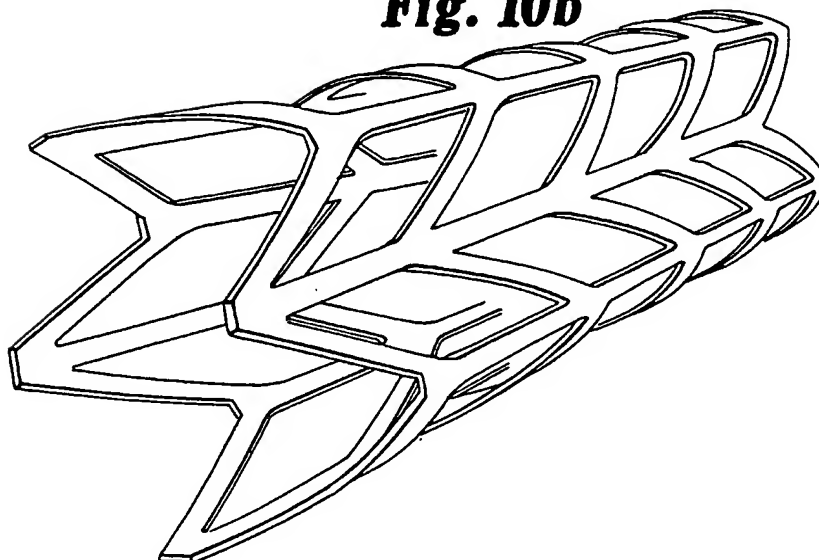


Fig. 10b



10/13

Fig. 10c

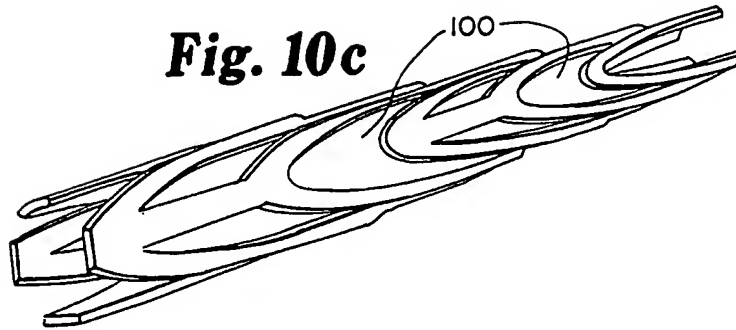
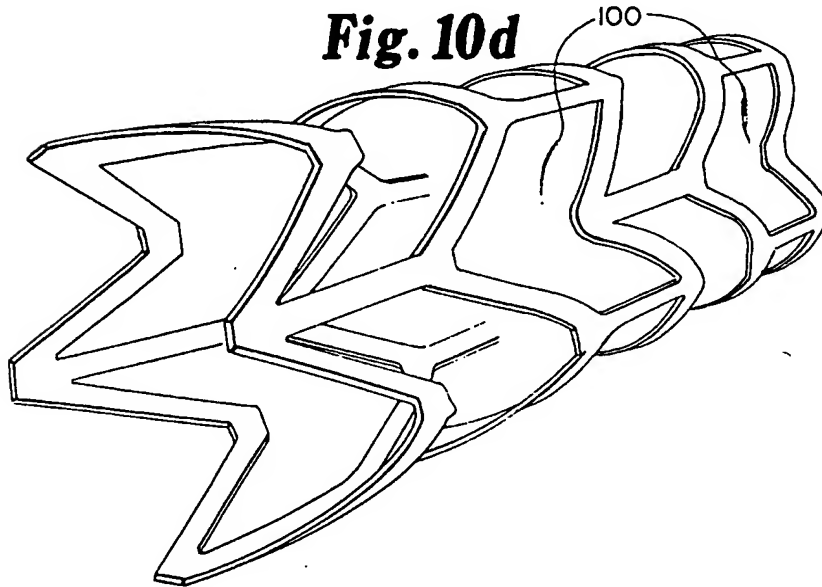


Fig. 10d



11/13

Fig. 11a

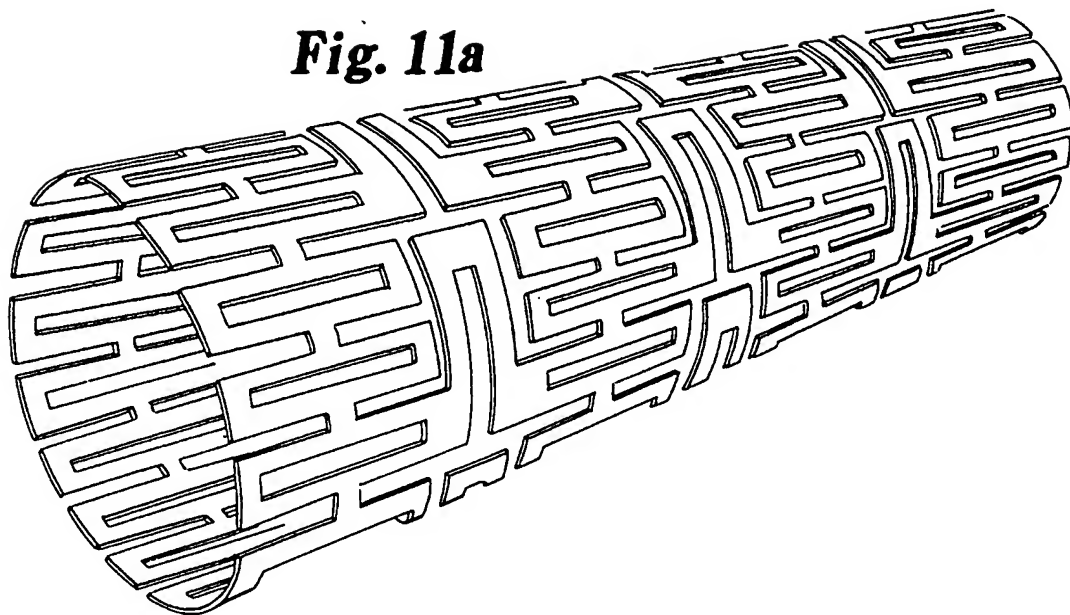
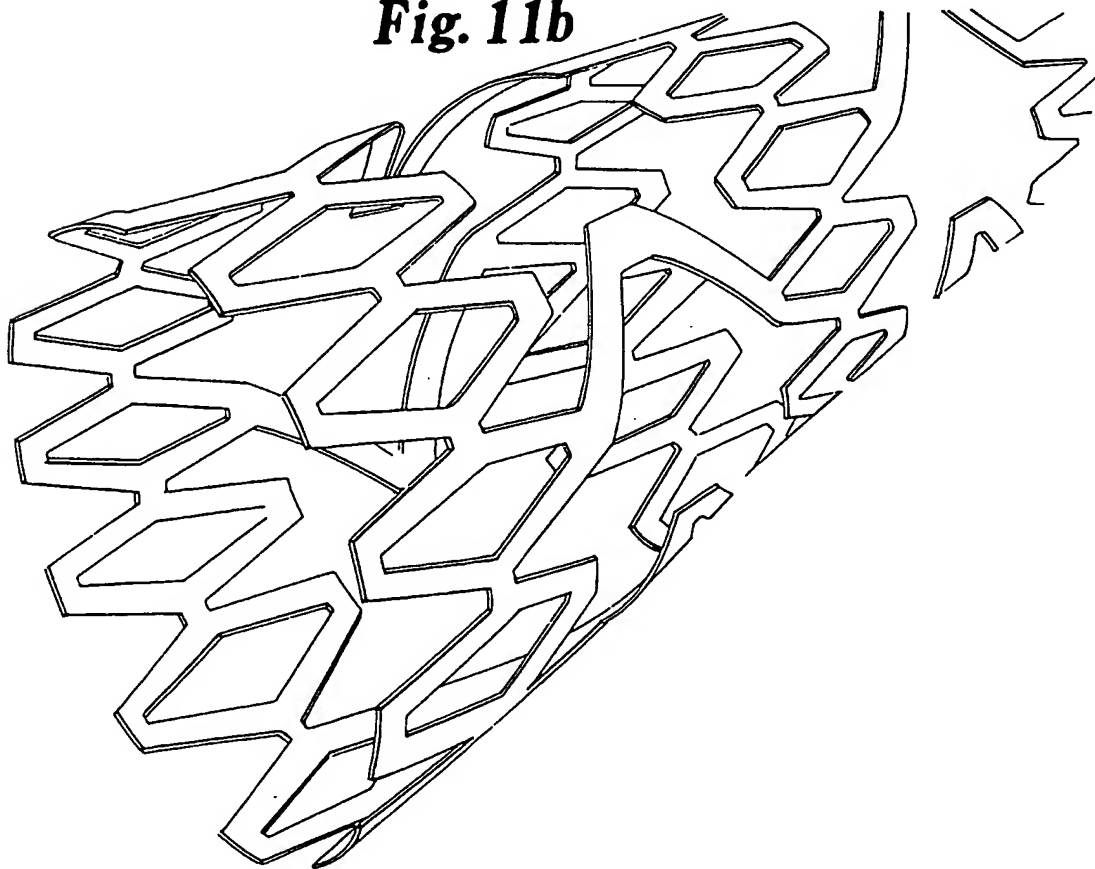


Fig. 11b



12/13

Fig. 12

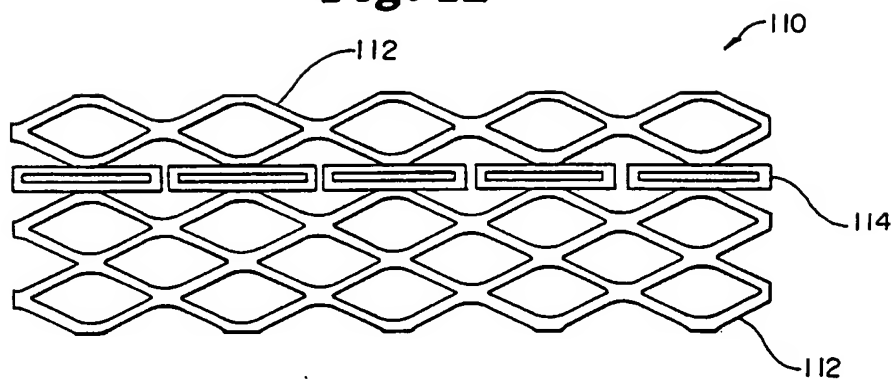


Fig. 13

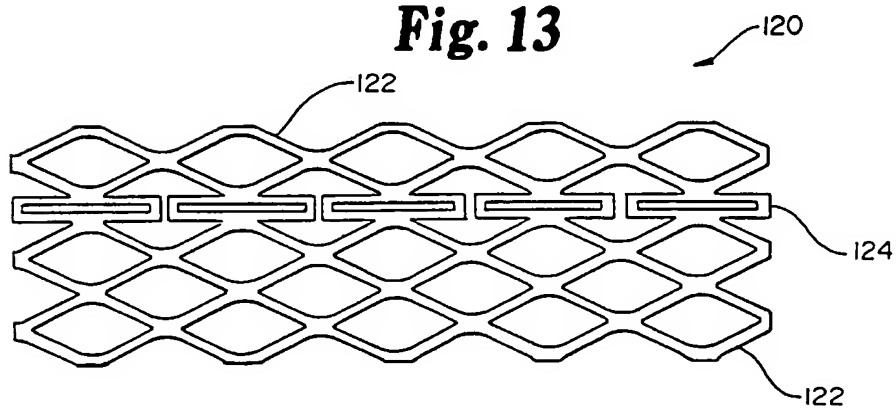


Fig. 14

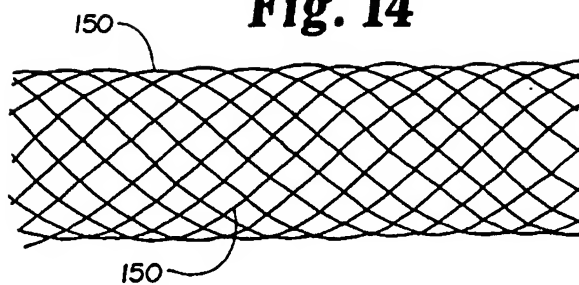


Fig. 15

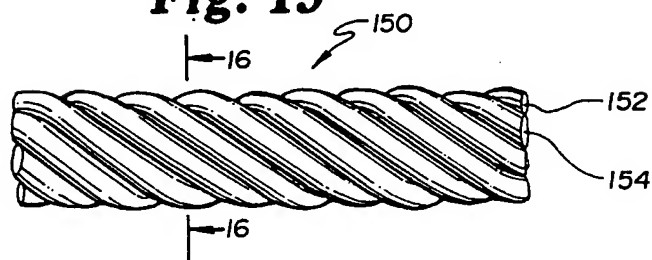
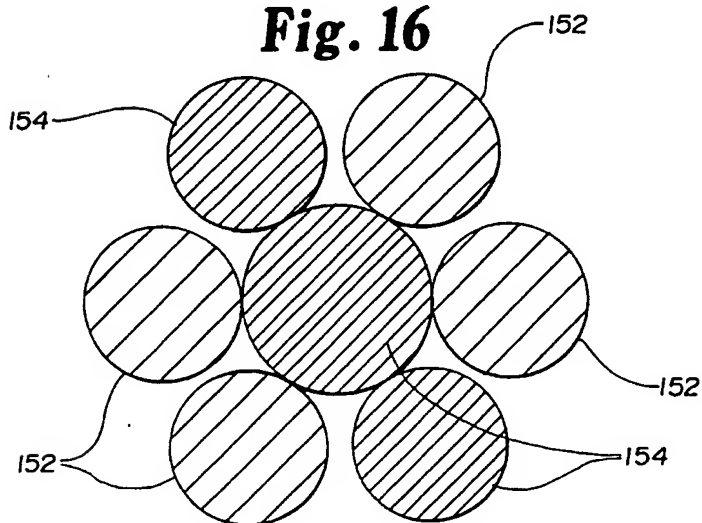


Fig. 16



INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 95/06228

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	FR,A,2 617 721 (NIPPON ZEON) 13 January 1989 see page 10, line 10 - page 14, line 33; figures 15-20 ---	6-9, 15-18, 20,21
A	GB,A,2 175 824 (BARRY) 10 December 1986 see abstract; figures ---	6,9,15, 17,20,21
A	WO,A,94 03127 (WILLIAM COOK EUROPE) 17 February 1994 see page 14, line 20 - line 34; claims 5,6; figures 1,5 ---	6-9,12, 15-18, 20,21
	-/--	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *&* document member of the same patent family

Date of the actual completion of the international search

20 October 1995

Date of mailing of the international search report

30. 10. 95

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+ 31-70) 340-3016

Authorized officer

Klein, C

INTERNATIONAL SEARCH REPORT

Int ional Application No

PCT/US 95/06228

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO,A,92 19310 (ADVANCED CORONARY TECHNOLOGY) 12 November 1992 see the whole document ---	6-9,12, 15-18, 20,21
A	EP,A,0 364 787 (EXPANDABLE GRAFTS PARTNERSHIP) 25 April 1990 see figures 7,8 ---	13
A	EP,A,0 335 341 (EXPANDABLE GRAFTS PARTNERSHIP) 4 October 1989 see figures 7-10 ---	13
A	US,A,5 147 370 (MCNAMARA) 15 September 1992 see column 1, line 61 - line 63; claim 8 -----	18

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 95/06228

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
FR-A-2617721	13-01-89	JP-A-	1017658	20-01-89
		DE-A-	3823060	19-01-89
		US-A-	4969890	13-11-90

GB-A-2175824	10-12-86	NONE		

WO-A-9403127	17-02-94	AU-B-	4698493	03-03-94
		CA-A-	2141208	17-02-94
		EP-A-	0653924	24-05-95
		PL-A-	307260	15-05-95

WO-A-9219310	12-11-92	US-A-	5197978	30-03-93
		CA-A-	2109312	27-10-92
		EP-A-	0585326	09-03-94
		JP-T-	6507096	11-08-94

EP-A-364787	25-04-90	AU-B-	623438	14-05-92
		AU-B-	4248589	12-04-90
		JP-A-	2174859	06-07-90
		US-A-	5195984	23-03-93

EP-A-335341	04-10-89	US-A-	5102417	07-04-92
		AU-B-	633478	04-02-93
		AU-B-	3174289	28-09-89
		CA-A-	1330186	14-06-94
		JP-A-	1299550	04-12-89

US-A-5147370	15-09-92	AU-A-	2237792	12-01-93
		EP-A-	0588959	30-03-94
		WO-A-	9222263	23-12-92

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☒ FADED TEXT OR DRAWING
- ☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☐ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.